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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,809	02/05/2004	Joel E. Bernstein	41957-102748	5946

23644 7590 04/04/2008

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
04/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/772,809	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments over the 35 USC 112, first paragraph rejection have been fully considered and are not found persuasive. In particular, Applicants argue that the claims 13 and 16 teach unit doses of the non-narcotic analgesic and tricyclic antidepressant, which differ from the daily dose range taught in the specification in paragraphs 0011 and 0012. Applicants specifically point to the Examples, in which the patients in the examples took unit doses of the two compositions. In two of the examples (Examples 1 and 3) the patient took one dose of the combination and in Example 2, the patient took twice daily doses of the combination.

While the difference between the daily dose range taught in the specification and the unit dose taught in the examples is fully understood, the Examiner maintains that the claims contain subject matter that was not described in the specification in such a way to convey to one of ordinary skill in the art. In particular, daily dose ranges were taught for the non-narcotic analgesic and tricyclic antidepressant. If converting the daily dose range to unit dose forms, one would need to know how many times per day that the daily dose is being administered in the ranges taught. The specification does not teach that, but only teaches the daily dosage amount. It is recognized that the examples teach unit doses administered once per day and twice per day. These particular doses do fall within the range of daily doses taught (if converted into unit dosage); however, the unit dose ranges within claims 13 and 16 do not fall within the daily dose ranges as taught. For example, claim 13 claims a non-narcotic analgesic administered in unit doses of from about 25 mg to about 1 gm. The broadest daily

dosage range taught in the specification is 0.5 grams to about 2.6 grams daily for a typical adult. If there were two unit doses given per day, then the unit dose range would be 250 mg to about 1300 mg. Because it is unclear how many daily doses are being taught within the range however, it is not clear what the unit dose range would be. Accordingly, the rejection is being maintained.

Applicant's arguments over the 35 USC 102(b) rejection have been fully considered and are not found persuasive. In particular, Applicants argue that Caruso does not teach a combination of cyclic antidepressants and non-narcotic analgesics but teaches a combination of antidepressants and a nontoxic NMDA receptor antagonist. Applicants further feel that the interpretation of the case law concerning the meaning of "consisting essentially of" language. Applicants further argue that one of skill in the art would expect that an NMDA receptor blocker would be required to achieve pain relief with the antidepressant.

In response to the above arguments, it is noted by the Examiner (as well as the Applicant in the response) that the case law meaning of "consisting essentially of" means that it includes only materials specified in the claim "and those that do no materially affect the basic and novel characteristics of the claimed invention". It is pointed out that Caruso teaches that the nontoxic NMDA receptor antagonist is given in an amount to potentiate the neuropathic pain-alleviating activity of the antidepressant (page 2, lines 13-18). Further, Caruso teaches unit dosage forms comprised of an antidepressant and non-narcotic analgesics with the NMDA receptor blocker (see Examples 29, 31, 35-37 and 39-40). Accordingly, it is determined that the NMDA

receptor antagonist does not materially affect the overall composition because its role is for potentiation of the antidepressant. Further, compositions are taught that include a non-narcotic analgesic with the antidepressant. Accordingly, the rejection is proper and is maintained.

Applicant's arguments over the 35 USC 103 rejection over Kakuyama et al. have been considered and are not found persuasive. In particular, Applicants argue that Kakuyama does not teach administering a tricyclic antidepressant and a non-narcotic analgesic one after the other. Further, Applicants question why one of skill in the art would give 2 drugs if each singly was expected to achieve the same result of pain relief.

In response to the above arguments, it is noted that Kakuyama et al. teach that naproxen and amitriptyline were administered to patients each night for a duration of six weeks. This is deemed to meet the claim limitation of a separate preparation taken one right after the other because this is a broad claim limitation. It is not clear what the time frame is in which each compound is taken. Accordingly, if a person takes a combination medication that is to work simultaneously for a condition at night, they are taking the combination together or separately but around the same time. Furthermore, one would combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). In particular, one would expect that the combination of the two compounds would have superior analgesic properties. Furthermore, Kakuyama teaches the

administration of the two compounds as discussed. Because Applicants have broadened the claim limitation, this rejection is now being used as a 35 USC 102(b) rejection.

Applicant's arguments over the 35 USC 103 rejection over Crawford in view of Lombardino have been considered and are not found persuasive. In particular, Applicants argue that Crawford teaches a non-steroidal anti-inflammatory drug with an antidepressant, and in particular piroxicam. Applicants assert that the present claims do not include a non-steroidal anti-inflammatory drug. It is further argued that the combination of the references does not present a prima facie case because the references do not cover the 2 claimed ingredients.

In response to the above arguments, it is noted that a non-steroidal anti-inflammatory drug is a non-narcotic analgesic, of which includes opioids. Though claim 9 claims a non-narcotic analgesic broadly, it is noted that claim 14 further limits a non-narcotic analgesic to acetaminophen and non-steroidal anti-inflammatory drugs. Accordingly, the rejection is maintained.

Due to Applicants amendments, the following modified rejections are given below.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification as originally filed does not provide support for a composition having a daily dose of 2.5 – 10 mg of doxepin as recited in claim 11, a non-narcotic analgesic in "unit doses of from about 25 mg to about 1 mg," as recited in claim 13, or a composition having a tricyclic antidepressant "in unit dosages containing 10 mg or less," as in claim 16. Instead, the specification teaches that the non-narcotic analgesic may be provided in amounts of from 0.5 grams to 2.6 grams daily (see paragraph 00010, in particular), but does not teach a composition having the smaller range of from 25 mg to 1 gm of non-narcotic analgesic, as recited in claim 13. The specification also teaches that suitable daily dosages of the tricyclic antidepressant may be in the range of about 2.5 mg to about 25 mg daily (see paragraph 00011, in particular), but does not teach specifically providing 2.5 – 10 mg of doxepin or providing the tricyclic in range of 10 mg or less, as recited in claims 11 and16. Accordingly, as claims 11, 13 and 16 are not fully supported by the

specification as originally filed, these claims are deemed to add impermissible new matter, and are rejected under 35 U.S.C. 112, first paragraph. Appropriate correction is required.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank S. Caruso, published November 12, 1998.

Caruso teaches treating neuropathic pain with a composition having an antidepressant (see abstract, in particular). Caruso teaches that the antidepressant can be a tricyclic antidepressant such as imipramine hydrochloride, doxepin hydrochloride, among others (see page 4, lines 1-19, in particular). Caruso teaches that an oral method of administration can be employed, and the composition may be provided as tablets or hard capsules, which are pharmaceutically acceptable vehicles (see page 6, lines 5-12, in particular). Caruso furthermore teaches that the composition can have a non-narcotic analgesic such as acetaminophen or naproxen (see page 7, lines 10-24, in particular). Caruso also teaches that the composition can be formulated to provide a desired dosage level of the components per day, and teaches formulating with

pharmaceutically acceptable ingredients and excipients (carriers) (see page 5, lines 20-25 and page 6, lines 10-25, in particular). Caruso teaches that the dosage forms be coadministered in a single dosage form (page 6, lines 5-12).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 9-15, Caruso teaches exemplary tablet dosage forms having antidepressant drugs and an additional active component that is a non-narcotic analgesic (see page 10, lines 5-37, in particular). Regarding claims 11-12 and 14-15, Caruso teaches that the tablet form can comprise compositions with 25 mg of imipramine hydrochloride and 325 mg of aspirin or acetaminophen (see examples 36 and 37, in particular). Thus, Caruso teaches the composition having the claimed tricyclic antidepressant compounds and non-narcotic analgesics, and also teaches the claimed pharmaceutically acceptable vehicle.

Regarding claims 9-10, Caruso's teaching of 25 mg of imipramine hydrochloride is considered to meet the limitation of being from "about" 2.5 mg to "about" 25 mg daily as recited in claim 10.

Regarding claims 9, 13 and 17, Caruso's teaching of 325 mg of acetaminophen is considered to meet the limitation of being a "standard dose" of non-narcotic analgesic compound as claimed, because it falls within the range of "about 0.5 grams to about 2.6 grams," in accordance with the Applicants' guidance of a suitable "standard dose," which is set forth in the second full paragraph on page 3 of Applicants' specification. In particular, 325 mg of acetaminophen is considered to be within the range of "about" 0.5 grams to "about" 2.6 grams, as set forth by Applicants, as well as the dose of from about 25 mg to about 1 gm as in claim 13, and about 50 mg to about 2.6 grams, as recited in claim 17.

Accordingly, the tablet dosage forms taught by Caruso anticipate the compositions of claims 9-15 and 17.

Claims 9-11, 13-14 and 17 are rejected under 35 U.S.C. 103(b) as being anticipated over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128.

Kakuyama et al. teaches treatment of chronic pain with antidepressants, noting that the efficacy of treatment of chronic pain with antidepressants has been assessed in many randomized controlled studies, and that tricyclic antidepressants are the first line treatment for chronic pain such as postherpetic neuralgia and painful diabetic

neuropathy, and are also effective for migraine and chronic tension-type headache (see abstract, in particular).

Kakuyama et al. teaches that patients suffering from fibromyalgia achieved significant improvement in their condition after receiving naproxen (an NSAID) in an amount of 1000 mg/day and amitriptyline in an amount of 25 mg each night, for a duration of six weeks (see page 125, right had column fourth full paragraph, in particular). Thus, Kakuyama et al. teaches the desirability of providing a non-narcotic analgesic in an amount that meets the limitation of being a "standard dose," as defined by Applicants on page 3 of the specification, as well as recited in instant claim 17, and administering the combination separately one right after the other (as recited in claim 9).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 11 and 14, Kakuyama et al. teaches providing amitriptyline and naproxen (and NSAID), and thus teaches providing the tricyclic antidepressant and NSAID, as recited in the claims.

Regarding claims 13 and 16, it is noted that Kakuyama et al. teaches a daily dosage of amitriptyline and naproxen that is efficacious in the treatment of fibromyalgia, as discussed above.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128, as applied to claims 9-11, 13-14 and 16-17 above, and further in view of WO 98/50044 to Caruso et al, published November 12, 1998.

Kakuyama et al. is applied as discussed above, and renders obvious a composition comprising amitriptyline and a "standard dose" of naproxen for the treatment of fibromyalgia.

Kakuyama et al. does not specifically teach providing the amitriptyline in the form of one of the acid addition salts as recited in claim 12. Kakuyama et al. also does not specifically teach the pharmaceutically acceptable vehicles such as tablets, capsules, caplets, etc, as recited in claim 15.

Caruso et al. teaches that it is known to provide the anti-depressant amitriptyline as a pain-relieving agent in the hydrochloride salt form (see page 4, in particular). Caruso et al. also teaches that it is known to deliver drugs such as antidepressants in pharmaceutically acceptable forms such as tablets or hard capsules (see page 6, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the hydrochloride salt form of the amitriptyline as taught by Caruso et al, as well to provide the amitriptyline and naproxen combination in the form of a tablet or hard capsule, in the composition and method of Kakuyama et al, because Kakuyama et al. teaches that the combination can be suitably administered for the treatment of fibromyalgia, whereas Caruso et al. teaches that the hydrochloride salt form and tablet of hard capsules are suitable forms for the administration of the pharmaceutical drugs. Accordingly, one of ordinary skill in the art would have been motivated to provide the hydrochloride salt form and tablet or capsule dosage form with the expectation of achieving a composition suitable for

pharmaceutical administration for the treatment of fibromyalgia. Accordingly, claims 12 and 15 are obvious over the teachings of Kakuyama et al. in view of Caruso et al.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over WO 98/50044 to Caruso et al, published November 12, 1998.

Caruso et al. is applied as discussed above, and teaches compositions for alleviating pain comprising an antidepressant (see abstract, in particular). Caruso et al. also teaches that the pain relief composition can also contain other analgesics such as acetaminophen and aspirin (see page 7, in particular), and further exemplifies a unit dosage form containing 25 mg of imipramine hydrochloride (tricyclic antidepressant), and 325 mg of either acetaminophen or aspirin (analgesic) (see Examples 36-37, in particular).

Caruso et al. does not specifically teach a dosage form having 10 mg or less of tricyclic antidepressant, as recited in claim 16.

However, Caruso et al. teaches that the desired dosage of the tricyclic can be determined through routine experimental testing, and can be optimized relative to the dosage level of an NMDA receptor antagonist being concomitantly administered (see page 5, in particular). Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize

the amount of tricyclic antidepressant provided in the composition, according to the guidance provided by Caruso et al, to provide a composition having desired properties, such as desired synergistic operation with the NMDA receptor antagonist. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955).

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,579,846 to Crawford et al, issued April 1, 1986, in view of U.S. Patent No. 4,434,164 to Joseph G. Lombardino, issued February 28, 1984.

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant) (see abstract and column 3, lines 45-58, in particular). Crawford et al. teaches that the piroxicam can be provide in a range of 0.1 to 1 mg/kg/day, whereas the second ingredient, such as doxepin, can be provided separately in an amount that is generally lower than the dosages typically specified in the prior art (see column 3, lines 45-55, in particular). Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed alone (see column 3, lines 55-68, in particular). That is, Crawford et al. teaches that the combined formulation could comprise the (i) 0.1 mg/kg/day dose of piroxicam with (ii) the lower

dose of doxepin that is taught by Crawford et al. as being provided if the drugs are administered alone (i.e. not in combination, separately). Crawford et al. also exemplifies a treatment composition comprising 20 mg of piroxicam and 20 mg doxepin with lactose and hydroxypropyl methylcellulose (carriers), and teaches that a dosage of the piroxicam can be from 5-50 mg/day (see Example 9 and column 4, lines 1-10, in particular).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Crawford et al. does not specifically teach that the compositions as exemplified comprise a "standard dose" of a non-narcotic analgesic and a low dose of a tricyclic antidepressant, as recited in claim 9.

Lombardino teaches novel salts of piroxicam that provide anti-inflammatory activity (see column 1 line 1 through column 2 line 60, in particular). Lombardino teaches that a suitable dose of the piroxicam salt can be from 5 mg up to 1000 mg per day (see column 3, liens 18-25, in particular).

Accordingly, Crawford et al's dosage of 5 to 50 mg/day (see column 4, lines 1-10, in particular), falls within the dosage range as taught by Lombardino et al. to be useful for anti-inflammatory action, and thus is considered to be a "standard dose" of piroxicam. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the "standard" normal dose of piroxicam as taught by Crawford et al. and Lombardino, with a lower dose of doxepin, as taught by Crawford et al, with the expectation of providing a suitable anti-inflammatory composition for the treatment of gastric irritation.

Regarding claims 13 and 17, Crawford et al's teaching of 5 to 50 mg/day of piroxicam meets and/or overlaps with the limitation of being from "about 25 mg to about 1 gm," as in claim 13, and "about 50 mg to about 2.6 gm," as in claim 17. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of piroxicam provided in the composition, according to the guidance provided by Crawford et al, to provide a composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

Regarding claims 10 and 16, Crawford et al. teaches that the dosage of doxepin can be from 4 to 200 mg/day (see column 4, lines 5-10, in particular), and exemplifies a

composition with 20 mg, and thus meets the limitation of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of doxepin provided in the composition, according to the guidance provided by Crawford et al, to provide a composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

Regarding claim 11, Crawford et al. teaches providing doxepin, as recited in the claim. Regarding claim 12, Crawford et al. teaches that doxepin is marketed in the form of its hydrochloride salt (see column 3, lines 15-20, in particular), and thus it would be obvious to one of ordinary skill in the art to provide doxepin hydrochloride because Crawford et al. teaches that this is a doxepin form that is available on the market. Regarding claim 14, Crawford et al. teaches providing piroxicam, which is a non-steroidal anti-inflammatory. Regarding claim 15, Crawford et al. teaches that the composition can be provided as a tablet or capsule (see column 4, lines 15-20, in particular).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

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